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ALLERGAN USA, INC. and
ALLERGAN INDUSTRIE, SAS

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, VALEANT PHARMACEUTICALS INTERNATIONAL, INC., AND GALDERMA LABORATORIES, L.P.

Defendants.

Case No. SACV13-01436 AG (JPRx)

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT OF NO INVALIDITY FROM PRIOR USE

Judge: Hon. Andrew J. Guilford
Hearing: May 18, 2015 at 10:00 a.m.
Ctrm: 10D

Discovery cutoff date: May 15, 2015
Pretrial conference date: July 20, 2015

Trial date: August 4, 2015

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I. INTRODUCTION

Allergan's current motion seeks to narrow the case by eliminating a legally insufficient invalidity defense, thereby focusing the remaining issues for trial. Allergan's patents-in-suit cover the inventor's surprising discovery that he could create novel and non-obvious dermal filler compositions. At a high level, these compositions include, for example, hyaluronic acid (HA) crosslinked with BDDE and the anesthetic lidocaine, and they remain stable even after being heat-sterilized. Before the August 2008 filing date of the patents-in-suit, Allergan and Defendants sold HA/BDDE dermal fillers without lidocaine. Defendants have alleged that the patents are invalid as anticipated or obvious because doctors were supposedly mixing those prior dermal filler products with lidocaine sometime before August 2008. There are many problems with these alleged "prior uses," but this motion focuses on a single legal deficiency that warrants summary judgment—Defendants have not identified any corroborating evidence to support their prior use allegations.

Supreme Court and Federal Circuit precedent bar Defendants from alleging prior use without corroboration. These decisions repeatedly stress that oral testimony alone is too unreliable to constitute the clear and convincing evidence required to invalidate a patent. Despite this black-letter law, Defendants have not identified anything to corroborate a single pre-August 2008 prior use. The only "evidence" in their opening expert reports was the opinion of a chemistry expert, Dr. Prestwich, who said that someone else "told" him doctors were mixing. But he does not identify who told him that, and the only document he cited was a 2009 article that says nothing about pre-August 2008 practice.

Perhaps recognizing this problem, Defendants have tried to slip more support into a "rebuttal" report from a clinical expert, Dr. Nestor, who says that he was administering mixed compositions starting sometime before 2006. Allergan will soon be filing an *ex parte* application to strike that evidence as untimely because it was not referenced in Defendants' invalidity contentions and is not rebuttal at all—

Allergan's clinical expert said nothing about when clinicians began mixing HA/BDDE-dermal fillers with lidocaine in her opening report. That aside, Dr. Nestor still did not cite anything to corroborate his own alleged prior use. Instead, he references only an August 2009 Internet post, which contains vague hearsay statements from a different doctor about his own practice, not Dr. Nestor's. The Internet post is also untimely because it was not cited in Defendants' invalidity contentions. But even if one considers these late submissions, Defendants' allegations still rely only on legally deficient, uncorroborated oral assertions. This Court should thus streamline the trial and prevent Defendants from arguing—without the required corroboration—their untimely prior use defense to the jury.

II. STATEMENT OF FACTS

Allergan's patents-in-suit, Nos. 8,450,475 and 8,357,795, cover stable, sterile dermal filler compositions that include hyaluronic acid (HA) crosslinked with BDDE and lidocaine. (*See* Doc. Nos. 84-1 & 84-2.) The Court's *Markman* order explains the technology in more detail—*e.g.*, what HA is, what "crosslinking" means, etc. We do not repeat that discussion here because those details are unnecessary to resolve the present motion.

Before Allergan's invention, existing HA/BDDE-dermal fillers did not include the anesthetic lidocaine. For example, Defendants introduced their first commercial HA/BDDE-dermal filler, Restylane®, in December 2003, and Allergan introduced its first commercial HA/BDDE-dermal filler, Juvederm® Ultra, in June 2006. (Countryman Decl., Ex. 1 at ¶¶ 40-42.) Neither included lidocaine. (*Id.*) As a result, some patients suffered significant pain when the products were administered. (*Id.* at ¶¶ 43-44.) For example, these dermal fillers are injected into the patient's face or lips using syringes, so patients experienced the pain that usually accompanies needle sticks. (*Id.*) Physicians thus needed an HA/BDDE-dermal filler with the desirable physical properties of existing products that could be injected without causing such pain. (*Id.* at ¶¶ 64-68.)

Despite having entered the HA/BDDE-dermal filler market first, and despite knowing that patient pain was a problem, Defendants had not addressed this issue. Instead, it was Allergan that devised the first way to create an HA/BDDE-dermal filler that included lidocaine, as reflected in an initial patent application filed in August 2008. (*See* Doc. Nos. 84-1 & 84-2.) Allergan incorporated this work into its new lidocaine-containing Juvederm® XC products, which received FDA approval on January 7, 2010. (*See, e.g.,* Ex. 2.) The Juvederm® XC products immediately improved patient comfort and substantially raised the standard of care. (Ex. 1 at ¶¶ 64-68.) In 2013, the Patent Office issued Allergan the '795 and '475 patents, which protect its surprising discovery that it could create stable, sterile HA/BDDE-dermal fillers with lidocaine. (*See* Doc. Nos. 84-1 & 84-2.) While Allergan's patents were pending, and after Allergan launched Juvederm® Ultra and Ultra Plus XC, Defendants launched their lidocaine-containing products—Restylane® L and Perlane® L. (*See, e.g.*, Ex. 3.) Once its patents issued, Allergan brought this suit to address Defendants' infringement. (Doc. Nos. 1 & 84.)

Defendants do not argue that Allergan's patents do not cover their products. Instead, they have raised a plethora of arguments that the patents are invalid. One is that the asserted claims of the '795 patent are supposedly anticipated by an alleged prior art use of the old non-lidocaine containing HA/BDDE-dermal fillers Juvederm® Ultra and Restylane®. In particular, Defendants' chemistry expert, Dr. Prestwich, submitted an opening expert report stating that he "ha[s] been told" that doctors had been mixing the old non-lidocaine-containing Juvederm® and Restylane® products with lidocaine since before Allergan's initial patent application was filed in August 2008:

> I have been told that practitioners were mixing lidocaine and HA-BDDE dermal fillers before injection of the dermal filler from the period shortly after HA-BDDE fillers were approved and available on the market.

(Ex. 4 at ¶ 227.) He further states that he has "been told" that doctors injected the mixed substance into patients and that it remained sterile and effective:

> Once the lidocaine had been added, I have been told that practitioners would inject the sterile substance into their patients as they would with any dermal filler. I have been told that the product remained sterile and clinically useful before injection took place.

(*Id*. at ¶ 229.)

Prestwich's report never indicates who "told" him these things, and Prestwich does not claim to have personal knowledge of them, for he is not a medical doctor. Moreover, he does not cite any corroborating evidence that would establish doctors were mixing HA/BDDE-dermal fillers with lidocaine before August 2008. Instead, the only item he cites is a 2009 article from after Allergan's patent application. (*Id*. at ¶ 145.) But that 2009 paper does not say when this mixing started, much less that it started before August 2008. (Ex. 5 at VAL0059974.) Based on this uncorroborated hearsay, Dr. Prestwich opined that doctors' supposed practice of mixing the prior products and lidocaine and injecting it into patients is a prior use that anticipates Allergan's '795 patent. (Ex. 4. at ¶¶ 227-30 & Ex. 4 at pp. 30-32.)

Defendants' uncorroborated prior use allegations also carry over into Prestwich's obviousness analysis. He opined—again based only on what he was "told"—that pre-August 2008 mixing would have rendered the '475 and '795 patents obvious. The entirety of his analysis for the '795 patent is set forth below:

> 235. I have been told that practitioners were mixing lidocaine and HA-BDDE dermal fillers using connectors before injection of the dermal filler from the period shortly after the HA-BDDE fillers were approved and available on the market.
>
> 236. The successful practice of adding lidocaine to HA dermal fillers would make it obvious to a POSITA [person of ordinary skill in the art] that adding lidocaine during the manufacturing process was able to be done and could result in a final lidocaine-containing dermal filler that had the elements of the asserted claims in view of the common knowledge in the art about HA fillers and lidocaine as that described in this report. Variations on degree of crosslinking, concentration of lidocaine, and amount of free HA had all been disclosed in the prior art and would all be obtainable through experimentation.
>
> 237. For the foregoing reasons, the asserted claims of the '795 patent would be obvious in light of the pre-mixing of lidocaine with crosslinked HA dermal fillers of the Restylane and Juvederm families performed by practitioners.

(Ex. 4 at ¶¶ 235-37.) His analysis for the '475 patent is similar, and his claim charts likewise lack any citations to corroborating evidence. (*See id*. at ¶¶ 182-86 (same for '475 patent); *id.* at pp. 23-29 (obviousness chart for '475 claims); *id.* at pp. 33-36 (obviousness chart for '795 claims).)

Defendants did not identify any other evidence of the allegedly invalidating prior use by the deadline for opening expert reports. They offered no opening report from a clinician, even though Defendants bear the burden of proof on this invalidity defense. Their initial invalidity contentions made no mention of the defense whatsoever. And their final invalidity contentions simply contain the generic, conclusory assertion that practitioners were mixing HA/BDDE-dermal fillers with lidocaine, without identifying any specific people by name and without citing any documentary evidence to support this assertion. The full disclosure of this alleged public use in Defendants' invalidity contentions is as follows:

> Additionally, practitioners would pre-mix Restylane and Juvederm products with lidocaine before injecting into their patients. These combinations produced a clinically viable filler that remained sterile. This pre-mixing anticipates Claims 1, 3, and 8 of the '795 Patent.

(Ex. 6 at 15.) Moreover, Defendants' new claim charts in their final invalidity contentions are similarly conclusory, asserting, without any citation or factual support, that practitioners were pre-mixing lidocaine with prior dermal fillers before August 2008, as in the example below:

***Pre-mixing by Practitioners*:**

The '475 patent	Prior Art Evidencing Obviousness of '475 Patent Claims
Claim 1	
A stable, sterile soft tissue filler comprising: paragraph	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
a hyaluronic acid (HA) component comprising HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
uncrosslinked HA, wherein the HA component comprises greater than about 10% uncrosslinked HA by volume; and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
lidocaine combined with said crosslinked HA component.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.

(Ex. 7 at 46.)

Apparently recognizing their lack of evidence, Defendants have since tried to fill these gaps, but have again failed to provide the required corroborating evidence. In particular, two days ago (on March 23), Defendants submitted an untimely "rebuttal" report from a clinician, Dr. Mark Nestor, who claims that he was mixing lidocaine with HA/BDDE-dermal fillers since before 2006. The relevant portions of his report describing his alleged prior use are reproduced below:

> I and other doctors began pre-mixing lidocaine into Restylane (a process Dr. Lupo [Allergan's clinical expert] describes as "swishing") prior to 2006. This process is done by connecting separate sterile syringes of Restylane and 0.2ccs of 1 or 2% lidocaine (usually containing epinephrine) with a sterile head-to-head connector and mixing the substances back and forth between syringes. . . .
>
> Before the introduction of lidocaine into the Juvéderm, Restylane, and Perlane products in 2010, I and many other doctors pre-mixed lidocaine into the products.

(Ex. 8 at ¶¶ 45-46.)

But, again, Dr. Nestor does not cite any evidence to corroborate that ***he*** was supposedly mixing before 2006. Instead, Dr. Nestor cites a hearsay Internet posting from August 2009 in which some ***other*** Texas doctor also claims to have been mixing prior products with lidocaine. (*See* Ex. 8 at ¶ 46 n. 29, *citing* Ex. 9.) That posting does not relate to Dr. Nestor's practices at all (he is based in Miami). (*See* Ex. 9.) Defendants did not identify either Dr. Nestor or that post in their invalidity contentions. Indeed, Dr. Prestwich's report does not mention either of them.

III. LEGAL STANDARDS

A. The Summary Judgment Standard.

Summary judgment is appropriate where the record, read in the light most favorable to the non-movant, shows that "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). Material facts are those necessary to the proof or defense of a claim, as determined by substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual issue is genuine only "if the evidence is such that a

reasonable jury could return a verdict for the nonmoving party." *Id.*

B. A Patent Cannot Be Invalidated by an Alleged Prior Public Use Without Corroborating Evidence.

A patent is invalid as anticipated if it was "used by others in this country … before the invention" by the patent applicant or "in public use … more than one year prior to the application for patent." 35 U.S.C. §§ 102(a), (b). Likewise, a patent is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103.

"When the asserted basis of invalidity is prior public use, the party with the burden of proof must show that the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 737 (Fed. Cir. 2002). Defendants bear that burden of proof by clear and convincing evidence. *See* 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238 (2011).

"Generally, oral testimony of prior public use must be corroborated in order to invalidate a patent." *Juicy Whip*, 292 F.3d at 737-38. The Supreme Court has required corroboration because of "the unsatisfactory character of such testimony, arising from the forgetfulness of witnesses, their liability to mistakes, their proneness to recollect things as the party calling them would have them recollect them, aside from the temptation to actual perjury" and has warned that "[w]itnesses whose memories are prodded by the eagerness of interested parties to elicit testimony favorable to themselves are not usually to be depended upon for accurate information." *The Barbed Wire Patent*, 143 U.S. 275, 284 (1892). Although the rule is "perhaps prophylactic in application," it "provides a bright line for both district courts and the PTO to follow in addressing the difficult issues related to invention dates." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996).

When corroborating evidence is proffered, its sufficiency is assessed under the "rule of reason," by considering a variety of factors. *Juicy Whip*, 292 F.3d at 741. But, if no corroborating evidence is proffered at all, then the invalidity defense simply fails at the threshold, without recourse to those factors. *See, e.g.*, *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1369-70 & n.11 (Fed. Cir. 1999).

IV. ARGUMENT

A. Defendants' Uncorroborated Prior Use Defenses Are Insufficient.

Defendants' allegations of an invalidating prior public use are insufficient as a matter of law because they lack the required corroboration. Defendants' only timely submission on prior public use is a conclusory expert report from Dr. Prestwich that cites no evidence of pre-August 2008 mixing at all. Defendants' untimely report by Dr. Nestor is no better, because he does not his support his proposed oral testimony with corroboration (like contemporaneous notes or patient records) that could substantiate his own alleged prior use. Instead, he cites only an Internet post with more uncorroborated hearsay about the practices of a different Texas doctor. The Court should thus grant summary judgment eliminating all the anticipation and obviousness defenses based on alleged prior use.[†]

A couple exemplary cases will illustrate the corroboration requirement and show that Defendants do not meet it here. In *The Barbed Wire Patent*, 143 U.S. 275 (1892), the Supreme Court reversed an invalidity finding even though 24 witnesses had testified that the same type of barbed wire fence that was covered by the patent had been previously exhibited at an Iowa county fair. *See* 143 U.S. at 285. These witnesses included people who seemed perfectly believable—a boy who had been thrown against the fence and cut, and a marshal whose horse had been bloodied after being tied to the fence. *Id*. at 286-87. The district court had credited their testimony

[†] Allergan notes that it will prove an earlier "invention" date than the August 2008 filing at trial. But it is unnecessary to pursue that issue further to resolve the present motion because Defendants have no corroboration of a prior use before the August 2008 filing date.

because "no motive can be conceived of, that would induce so large a number of well-known persons to engage in such a conspiracy." *See Washburn & Moen Mfg Co v. Beat 'Em All Barb-Wire Co.*, 33 F. 261, 272 (C.C.N.D. Iowa 1888). Yet the Supreme Court reversed, observing that "almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny." *See* 143 U.S. at 284-85.

The Federal Circuit's precedent follows the same approach. For example, in *Woodland Trust v. Flowertree Nursery*, 148 F.3d 1368 (Fed. Cir. 1998), the Court reversed a finding of prior public use that had been based exclusively on uncorroborated oral testimony. There, four witnesses testified that the patented method had been previously used, and the district court credited them and invalidated the patent, explaining that it would have to conclude the witnesses were "deliberate perjurers" to conclude otherwise. *Id*. at 1370. The Federal Circuit reversed, holding that "uncorroborated oral testimony, particularly that of interested persons recalling long-past events, does not, of itself, provide the clear and convincing evidence required to invalidate a patent on this ground." *Id*. at 1369. The Court reaffirmed the vitality of *The Barbed Wire Patent*, especially because, these days, almost all commercial activity is reflected in written documents:

> The Supreme Court's view of human nature as well as human recollection, whether deemed cynical or realistic, retains its cogency. This view is reinforced, in modern times, by the ubiquitous paper trail of virtually all commercial activity. It is rare indeed that some physical record (e.g., a written document such as notes, letters, invoices, notebooks, or a sketch or drawing or photograph showing the device, a model, or some other contemporaneous record) does not exist.

Id. at 1373. The Court thus found the absence of any corroborating documents precluded a finding of invalidity as a matter of law: "With the guidance of precedent, whose cautions stressed the frailty of memory of things long past and the

temptation to remember facts favorable to the cause of one's relative or friend, we conclude that this oral evidence, standing alone, did not provide the clear and convincing evidence necessary to invalidate a patent on the ground of prior knowledge and use under § 102(a)." *Id*.

The Federal Circuit imposes the same corroboration requirement even if the witnesses alleging prior use are disinterested. For example, in *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354 (Fed. Cir. 1999), the Court reversed a finding that the patent was invalid based on the testimony of an uninterested witness who had authored an article in the area that disclosed all but one of the claim limitations and testified that he had practiced all the limitations, including the one missing from the article. *Id*. at 1364-66. The Court explained that "uninterested witnesses are also subject to the corroboration requirement," adding that a "witness who testifies to antedating the invention of the patent-in-suit can be expected to derive a sense of professional or personal accomplishment in being the first in the field, and in this sense is not uninterested in the outcome of the litigation, even if that witness is not claiming entitlement to a patent." *Id*. at 1367-68. The Court also distinguished between cases dealing with the sufficiency of corroborating evidence, which is analyzed under various factors, and cases in which there is no corroborating evidence at all: "In this case, the sole basis to support a determination of a prior public use was Jefferts' testimony concerning his own work; there was no evidence corroborative of this testimony at all." *Id*. at 1369-70. When there is no corroborating evidence at all, the testimony is necessarily insufficient as a matter of law, regardless of how well intentioned the witness may be:

> In the end, what we are left with is Jefferts' testimony concerning his alleged public use. Such evidence is insufficient as a matter of law to establish invalidity of the patent. This is not a judgment that Jefferts' testimony is incredible, but simply that such testimony alone cannot surmount the hurdle that the clear and convincing evidence standard imposes in proving patent invalidity.

Id. at 1370.

A final example is *Juicy Whip, Inc. v. Orange Bang, Inc.*, 292 F.3d 728 (Fed. Cir. 2008). There, the Court reversed a jury finding of invalidity and held the testimony of six witnesses insufficient as a matter of law where the alleged events occurred between 8-12 years before, the witnesses were connected to the defendant, and the only alleged corroboration (a purchase order) did not show whether a key claim limitation was present. *Id*. at 743. The Court was not necessarily distrustful of the witnesses' candor but simply applied the rule warning against reliance on oral testimony alone:

> We do not conclude that the witnesses below were not credible. Rather, with the guidance of precedent cautioning against the reliance on oral testimony alone, we hold that the evidence of record did not provide the clear and convincing evidence necessary to invalidate the patent for prior public knowledge.

Id.

Those cases fit this one like a glove and mandate summary judgment that Defendants' anticipation and obviousness defenses based on alleged prior use are legally insufficient. Defendants' only timely submission—Dr. Prestwich's opening report—is woefully inadequate. He does not even have personal knowledge of the allegedly invalidating use, and instead cites only (i) what someone "told" him and (ii) a 2009 article that is silent on what was occurring before August 2008. (Prestwich Report at ¶¶ 227-30, 145.) Defendants' other (untimely) submissions—*i.e.*, the relevant parts of the Nestor report and his belatedly cited Internet post—should be stricken for reasons Allergan will explain in a forthcoming *ex parte* application. But, even if considered, they are inadequate. Dr. Nestor does not cite any evidence to corroborate his assertion that he was mixing HA/BDDE-dermal fillers with lidocaine before August 2008. (Ex. 8 at ¶¶ 45-47.) He offers no patient records, no treatment notes, no contemporaneous publication describing his practice. Nothing. Instead, Dr. Nestor cites a 2009 Internet post in which a different doctor discusses that doctor's practices. But this post cannot corroborate Dr. Nestor's allegations about Dr. Nestor's use—it is talking about what the Texas doctor

supposedly did, not what Dr. Nestor did. Defendants have not offered any corroborating evidence to substantiate the Texas doctor's assertions either. That aside, the Texas doctor's assertions are inadmissible hearsay, which makes them irrelevant in any event.

This case thus falls squarely under *Finnigan*'s holding that uncorroborated testimony (or the statements of a hearsay declarant) cannot constitute the clear and convincing evidence required to invalidate a patent. Indeed, any alleged prior use would have occurred over 6 years ago, which is plenty of time for memories to fade or become confused, and Defendants' only witness is their interested expert. Moreover, as in *Woodland Trust*, this is the type of prior use that would have been documented if it actually occurred. Doctors meticulously document the procedures they perform on patients, so the absence of even a single patient record here speaks volumes. This is also a case where details matter. Many of the asserted patent claims require the dermal filler composition to meet specific requirements regarding stability, sterility, and the maintenance of a physical property—extrusion force—for at least 9-months. (*See* Doc Nos. 84-1 & 84-2.) Defendants' proposed oral testimony does not properly analyze these limitations, nor do their accompanying expert reports or claim charts. Even if it did, supporting documents would be required to make sure that witnesses were not misremembering the details, as in *The Barbed Wire Case, Finnigan*, and *Juicy Whip*, which cautioned that failure to corroborate the details of each claim limitation is fatal to an invalidity defense.

The bottom line is that Defendants have, at best, presented potential oral testimony from one witness (Nestor) and the unsupported hearsay assertions of a Texas doctor—far worse than the six witnesses in *Juicy Whip* or 24 witnesses in *The Barbed Wire Case*. Defendants' evidence is legally insufficient, and their anticipation and obviousness defenses based on the alleged prior use thus fail as a matter of law.

B. Defendants Cannot Cure Their Lack of Corroboration By Adding New Evidence in Response to This Motion.

It will be no answer for Defendants to try and fix their lack of corroboration by identifying new evidence in response to this motion, because any such new disclosures would be untimely. Defendants' "rebuttal" report from Dr. Nestor, which was served just two days ago, and his belated citation to the hearsay Internet post were already an untimely attempt to back-fill, as Allergan's forthcoming *ex parte* motion to strike them will explain. Defendants are likewise precluded both by this Court's Standing Patent Rules and the Federal Rules of Civil Procedure from adding anything further in their opposition to this motion.

For example, this Court's Standing Patent Rules required the Defendants to identify the details of any alleged prior use in their invalidity contentions, including the identity of any doctor who was alleged to have done it and the precise date when it supposedly occurred:

> Prior art under 35 U.S.C. § 102(b)/(a) shall be identified by specifying the item offered for sale or publicly used or known, ***the date the offer or use took place*** or the information became known, and ***the identity of the person or entity which made the use*** or which made and received the offer, or the person or entity which made the information known or to whom it was made known.

S.P.R. 2.5.1 (emphasis added). Yet Defendants' initial invalidity contentions did not include this defense at all, and, when it was belatedly added in the final contentions, Defendants did not provide any of the specifics required by the Rule. Instead, the final contentions generically allege that unspecified "practitioners" would pre-mix fillers and lidocaine, without saying who or when. (Ex. 6 at 15.) They do not identify either Dr. Nestor or the hearsay Internet post that he cites. They also do not identify any other allegedly corroborating documents, like patient records. But the rule required Defendants to disclose any of these materials with their Final Invalidity Contentions on February 17, 2015, and to have "good cause" for why none of this information was in their initial Invalidity Contentions. Having failed to do so, Defendants cannot add supporting corroboration now.

What is more, the Federal Rules of Civil Procedure required Defendants' invalidity expert to identify any corroborating evidence in his opening expert report. The Court's scheduling order sets the deadline for "Defendants' Expert Report on Issues Defendants have the burden of proof, including, but not limited to, Invalidity" as February 17, 2015. (Doc. No. 119 at 3.) Rule 26 required those expert reports to include "the facts or data considered by the witness in forming" the expert's opinions and "any exhibits that will be used to summarize or support them." Fed. R. Civ. P. 26(a)(2)(B)(ii)-(iii). Yet Defendants' only opening expert report presented these prior use invalidity theories based entirely on what an unnamed person "told" the expert and did not identify any other facts, data, or exhibits to support his conclusory assumptions about prior public use. Likewise, Defendants' untimely "rebuttal report" from Dr. Nestor on his own prior use did not include any corroborating patient records, even though these would be necessary to "support" his opinions. Defendants thus cannot add them now. Gap filling with new facts or data after the expert report deadline isn't permitted by the rules.

V. CONCLUSION

For the reasons above, the Court should grant partial summary judgment that Defendants' invalidity defenses based on the allegation that doctors pre-mixed prior HA/BDDE-fillers with lidocaine before August 2008 fail as a matter of law.

Dated: March 25, 2015

FISH & RICHARDSON P.C.

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Attorneys for Plaintiffs
ALLERGAN USA, INC. AND
ALLERGAN INDUSTRIE, SAS

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on March 25, 2015 to all counsel of record who are deemed to have consented to electronic service via the Court's CM/ECF system per Civil Local Rule 5.4. Any other counsel of record will be served by electronic mail, facsimile and/or overnight delivery.

/s/ Craig E. Countryman
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